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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,430	02/13/2006	Markus Hecker	DEBE:052US/10501403	9671

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,430	HECKER ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants amendments filed 8/9/2007 have been entered.

2. Claims 11 and 13-16 are amended.

3. Claims 1-10 are cancelled.

4. Claim 19 is new.

5. The rejection of claims 11-16 under 35 USC 101 is withdrawn.

6. The rejection of claims 11-12 under 35 USC 102(b) is withdrawn.

7. The rejection of claims 11, 13-15 and 17-18 under 35 USC 103(a) is withdrawn.

8. Claims 11-19 are examined in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chouini-Lalanne et al. (1998, Biochemical Pharmacology, Vol. 55, pgs. 441-446) and Ajmone-Cat et al. (2001, J. of Neuroscience Res., Vol. 66, pgs. 715-722).

For the purposes of this rejection, the term "pharmaceutical" is given no patentable weight. While the claimed formulation may be used in the manufacture of a pharmaceutical, the

claimed components that comprise the formulation would be indistinguishable from the prior art below.

Chouini-Lalanne et al. teach a formulation comprising supercoiled $\phi\chi$-174 DNA in 5 mM phosphate buffer at pH 7.4 and containing 10 mM NaCl and further comprising one of four different nonsteroidal anti-inflammatory drugs (NSAID) (pg. 442, col. 1 parag. 2 bridge col. 2 parag. 1 lines 1-4 and Fig. 1). Chouini-Lalanne et al. continue to teach that the $\phi\chi$-174 DNA was complexed with either Naproxen, Ketoprofen, Tiaprofenic acid or Indomethacin (pg. 442, Fig. 1). It is important to not that the instant claims contain no functional language nor indicate an intended use. The claims are drawn to a product which is a formulation comprising a nucleic acid and a nonsteroidal anti-inflammatory drug, wherein the formulation exists in a specific pH range and said drug is present in a specific concentration range.

Ajmone-Cat et al. teach that NSAIDs are among the most widely used therapeutic agents for the treatment of pain, fever, and inflammation (pg. 715, col. 2 parag. 1 lines 1-3). Ajmone-Cat teaches that flurbiprofen belongs to the class of drugs known as NSAIDs and that flurbiprofen inhibits PGE_2 production (pg. 716, col.1 parag. 2) which is a prime mediator of inflammation.

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to perform routine experiments to determine the concentration of chloride ions and the choice of and concentration of the non-steroidal anti-inflammatory drug. In the instant claims the concentrations claimed are from 5-100 mmol/l for chloride ions and 50-250 μmol/l for the non-inflammatory drug. The concentration ranges for the chloride ions would exist in any buffer used in the manufacture in the pharmaceutical and would be of normal physiological levels as

described in dependent claims 13, 14 and 19. With regard to the selection and range of the anti-inflammatory drug used in the claimed formulation the ordinary artisan, based upon the teachings of Chouini-Lalanne and Ajmone-Cat, would find it obvious to try different nonsteroidal anti-inflammatory drugs, such as indoprofen or flurbiprofen, at levels that would necessitate an anti-inflammatory action. See *In re Aller*, 105 USPQ 233 at 235 (CCPA 1955), which states "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Also see MPEP § 2144.05. In this case, the general conditions are disclosed in the prior art.

Furthermore it is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. In the instant case even though the invention is drawn to using different concentrations ranges, it is not deemed patentable and an improvement over the teachings discussed above by Chouini-Lalanne. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement

and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added). With regards to determining experimental parameters, such as time in culture, the court has held that "[d]iscovery of optimum value of result effective variable in known process is ordinarily within skill of art (*In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information

Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632

AMENDMENT TO THE CLAIMS

Listing of the Claims

The following listing of claims replaces all previous listings or versions thereof:

1-10. (Canceled)

11. (Currently amended) A pharmaceutical formulation comprising (a) a nucleic acid, ~~wherein said formulation comprises a pH value within the range from pH 6.2 to pH 7.0, and/or~~and (b) a nonsteroidal anti-inflammatory drug, wherein said formulation exhibits a pH value from pH 6.2 to pH 7.0, ~~a chloride ion concentration within the range from 5 to 100 mmol/l and/or provides a~~and wherein said nonsteroidal anti-inflammatory drug ~~with~~is present at a concentration within the range from 10 to 500 μmol/l.

12. (Previously presented) The formulation according to claim 11, wherein the pH value is 6.5 or 7.0.

13. (Currently amended) The formulation according to claim 11, wherein the chloride ~~ions have a~~ion concentration ~~within the range~~is from 5 to 50 mmol/l.

14. (Currently amended) The formulation of claim 11, wherein the chloride ~~ions have a~~ion concentration ~~within the range~~is from 5 to 10 mmol/l.

15. (Currently amended) The formulation of claim 11, wherein the nonsteroidal anti-inflammatory drug ~~has~~is present at a concentration within the range from 50 to 250 μmol/l.

16. (Currently amended) The formulation of claim 11, wherein the nonsteroidal anti-inflammatory drug ~~has~~is present at a concentration of 100 μmol/l.

17. (Previously presented) The formulation claim 11, wherein the nonsteroidal anti-inflammatory drug is flurbiprofen or indoprofen.

18. (Previously presented) The formulation according to claim 1, further comprising a carrier substance or additive.

19. (New) The formulation according to claim 11, further comprising a chloride ion concentration within the range from 5 to 100 mmol/l.